# EXHIBIT 3

**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**MARSHALL DIVISION**

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| **ERFINDERGEMEINSCHAFT UROPEP GbR,**<br><br>**Plaintiff,**<br><br>**vs.**<br><br>**ELI LILLY AND COMPANY, and BROOKSHIRE BROTHERS, INC.,**<br><br>**Defendants.** | **Case No. 2:15-cv-01202-JRG-RSP** |

# DEFENDANTS' AMENDED INVALIDITY CONTENTIONS

Pursuant to Local Patent Rule ("P.R.") 3-6, Defendants Eli Lilly and Company and Brookshire Brothers, Inc. ("Defendants") hereby serve their Amended Invalidity Contentions on Plaintiff Erfindergemeinschaft UroPep GbR ("Plaintiff"). These Amended Invalidity Contentions address the claims of U.S. Patent 8,791,124 (the '124 Patent) that have been asserted in Plaintiff's Local Rule 3-1 and 3-2 Disclosures (Plaintiff's original "Infringement Contentions") served on November 24, 2015 and Plaintiff's "Updated"[1] Infringement Contentions served on November 12, 2016 (Plaintiffs' "Amended Infringement Contentions"), *viz.* Claims 1 and 3 of the '124 Patent (the "Asserted Claims").

## I. INTRODUCTION AND RESERVATION OF RIGHTS

These Amended Invalidity Contentions are based on information reasonably known and available to Defendants at this time and are subject to revision as discovery, pre-trial and trial

[1] Although styled as "updated" infringement contentions, Defendants understand that Plainitff intended this document to be its Amended Infringement Contentions under Local Patent Rule 3-6.

proceeds. Moreover, these Amended Invalidity Contentions are based on the limited information provided by Plaintiff in its original and Amended Infringement Contentions. Despite obligations under the Local Rules and the Court's Scheduling Order, Plaintiff's original and Amended Infringement Contentions fail to apply the Court's claim construction rulings or provide sufficient detail as to how the claim language in fact applies to the alleged activities of the Defendants. Plaintiff's original and Amended Infringement Contentions also fail to show how each individual Defendant can be liable for inducement of infringement of the claimed method of treatment in the '124 Patent or direct infringement of the identified claims. Defendants accordingly reserve the right to amend and/or supplement these Amended Invalidity Contentions, including the right to identify additional information concerning the prior art identified herein as well as additional prior art after entry of this Court's claim construction of the Asserted Claims.

Furthermore, despite the nominal close of fact discovery, Defendants still have not yet received all relevant discovery, including documents, from Plaintiff or the named inventors of the '124 patent (each of whom were allegedly "partners" of Plaintiff), relating to the claims or defenses in this action. For example, Plaintiff has not produced documents evidencing the conception or reduction to practice of any purported invention claimed in the '124 Patent or documents that may reflect one or more of the named inventors publications or work relating to the claimed subject matter of the '124 Patent, which may constitute prior art under, *inter alia*, 35 U.S.C. §§ 102(b), (f), (g), and/or 103. To the extent that Defendants obtain additional information through discovery of Plaintiff or of third parties which may impact the scope and meaning of the claims and/or these Amended Invalidity Contentions, Defendants reserve the right to further supplement or amend these Amended Invalidity Contentions. Defendants also reserve the right to introduce and use such supplemented materials at trial.

As noted above, although certain claim terms in the '124 Patent have been construed by the Court, Plaintiff has failed to apply the Court's complete claim constructions in their Amended Infringement Contentions and opening Expert Reports on Infringement ("Infringement Reports"). Additionally, as reflected in Defendants' opening Expert Reports on Invalidity dated November 18, 2016 ("Invalidity Reports"), which are incorporated herein by reference in their entirety, the Court's construction of "inhibitor of phosphodiesterase (PDE) V" creates fundamental ambiguities in claim scope. Plaintiff has not addressed these ambiguities in its Amended Infringement Contentions or Infringement Reports. Thus, these Amended Invalidity Contentions cannot reasonably seek to respond to a case that is not complete or predict how Plaintiff may seek to amend or supplement its positions in the future to fill their evident deficiencies. Consequently, these Amended Invalidity Contentions are not and should not in any way be seen as waivers of Defendants' objections to Plaintiff's inadequate and insufficient Amended Infringement Contentions and Infringement Reports; admissions or adoptions of any particular claim scope or construction; or admissions that any particular limitation is met in any particular way by the alleged conduct that Plaintiff apparently contends infringes the Asserted Claims. Nothing herein should be construed as an admission that Defendants agree with Plaintiff's reading of the Asserted Claims as described in the Amended Infringement Contentions or Infringement Reports, or any implied construction of the Asserted Claims by Plaintiff in Plaintiff's Amended Infringement Contentions or Infringement Reports. Accordingly, Defendant's Amended Invalidity Contentions, including the invalidity claim charts, may reflect alternative positions as to claim construction and scope.

Based on the information available at this time, and the literal scope of the Asserted Claims read in view of the intrinsic evidentiary record, Defendants contend that the Asserted

Claims are invalid under 35 U.S.C. § 102 (specifically, subparts (a), (b), (e), (f) and (g)) and/or § 103 (specifically, subpart (a)) as being anticipated by or rendered obvious by prior art as set forth in Defendants' Invalidity Expert Reports, which are incorporated herein by reference, and Defendants' original Invalidity Contentions. Furthermore, in light of the ambiguities in the Court's construction of "inhibitor of phosphodiesterase (PDE) V" and Plaintiff's failure to address those ambiguities, Defendants also incorporate and restate each assertion and analysis made in their original Invalidity Contentions under Local Patent Rule 3-3 and 3-4, dated January 26, 2016. Although Defendants oppose any attempt by Plaintiff to change its infringement allegations and/or to supplement or alter its Amended Infringement Contentions and/or Infringement Expert Reports, as such attempts would prejudice Defendants, Defendants reserve the right to cite, present or rely upon any of the assertions and analyses made in their original Invalidity Contentions. Defendants also reserve the right to amend or supplement their Invalidity Expert Reports, should it become necessary.

Furthermore, prior art not included in this disclosure or the original Invalidity Contentions, whether or not now known to Defendants, may become relevant depending on any future claim constructions (or modifications of current claim constructions) adopted by the Court. Defendants' ongoing investigation may also uncover additional prior art references or activities. Any obviousness combinations of references under 35 U.S.C. § 103 that are provided herein, in Defendants' Invalidity Expert Reports or in Defendants' original Invalidity Contentions are not intended to be exhaustive. Additional obviousness combinations of the references identified below are possible, and Defendants reserve the right to use any such combinations in this litigation.

As noted herein, Defendants contend that the Asserted Claims do not satisfy one or more requirements of 35 U.S.C. § 112. Nevertheless, in the invalidity claim charts, Defendants have applied the claim scope attributed by Plaintiffs in their Amended Infringement Contentions and Infringement Expert Reports for terms Defendants contend are indefinite and/or otherwise fail to meet the requirements of 35 U.S.C. § 112. The application of prior art in these Amended Invalidity Contentions should not be construed as an admission that Defendants agree that any of the Asserted Claims satisfies the requirements of 35 U.S.C. § 112.

Finally, Defendants contend that the Asserted Claims are directed to laws of nature that are not eligible for patenting. The Asserted Claims are, therefore, invalid under 35 U.S.C. § 101. In the invalidity claim charts, Defendants have applied the claim scope attributed by Plaintiffs in their Amended Infringement Contentions and Infringement Expert Reports to the claims at issue. The application of prior art in these Amended Invalidity Contentions should not be construed as an admission that Defendants agree that any of the Asserted Claims satisfies the requirements of 35 U.S.C. § 101.

The foregoing statements and reservations of rights are hereby expressly incorporated by reference in their entirety into each of the disclosures below, into the invalidity charts served as Exhibits with the original Invalidity Contentions, and into each disclosure corresponding to each element of every claim whether contained herein or within any exhibit.

## II. STATEMENT AS TO ALLEGED PRIORITY DATE OF THE '124 PATENT

Plaintiff contends that all of the Asserted Claims are entitled to "a priority at least as early as July 19, 1997" (*see* Plaintiff's Infringement Contentions at 4), which is the filing date of application No. PCT/EP97/03617, to which the '124 Patent claims priority. These Amended

Invalidity Contentions should not be taken as an admission that Plaintiff's alleged priority date is correct or admitted as such by Defendants either expressly or on an implied basis.

Indeed, based on the information presently available, Defendants contend that Plaintiff is not entitled to a priority date of July 19, 1997, the filing date of application No. PCT/EP97/03617, because, *inter alia*, its inventors did not have possession of the claimed invention as it has been construed by the Court. The '124 Patent issued from application No. 13/339,561 filed on December 29, 2011, which is a continuation of application No. 10,443,870 filed on May 23, 2003, now U.S. Patent No. 8,106,061, which is a continuation of application No. 09,462,090 filed as application No. PCT/EP97/03617 on July 19, 1997, now abandoned. Defendants contend that the Asserted Claims are not entitled to the benefit of the filing date of the '124 Patent (or the priority date of the '090 application or any other application noted in the priority claim) because the subject matter of the Asserted Claims is not disclosed in the manner required by 35 U.S.C. § 112, first paragraph, in the earlier filed related patents or applications. *See, e.g., In re NTP, Inc.*, 654 F.3d 1268, 1277 (Fed. Cir. 2011).

> Nothing in 35 U.S.C. §§ 301 *et seq.* entitles a patentee to a claim of right to its earliest priority date. Under § 120, a patent is entitled to the priority date of an earlier filed application if (1) the written description of the earlier filed application discloses the invention claimed in the later filed application sufficient to satisfy the requirements of § 112; (2) the applications have at least one common inventor; (3) the later application is filed before the issuance or abandonment of the earlier filed application; and (4) the later application contains a reference to the earlier filed application. In addition, if the later filed application claims priority through the heredity of a chain of applications, each application in the chain must satisfy § 112. *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571 (Fed. Cir. 1997).

*In re NTP*, 654 F.3d at 1277. Defendants contend that Plaintiff cannot claim priority to the PCT application filed July 9, 1997 (or any other application in the chain) because the Asserted Claims as construed do not have the requisite support to claim priority. Thus, the earliest priority date

available for the '124 Patent is December 29, 2011, which is the the filing date of application No. 13/339,561 that eventually issued as the '124 Patent.[2]

For a patent claim to be entitled to the filing date of an earlier application, the earlier application must "contain a written description of the [later-claimed] invention, and the manner and process of making and using it." 35 U.S.C. §§ 112, 119-121 (2011). *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed.Cir.1997). *See generally Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, No. 2008–1248, 2010 WL 1007369 (Fed.Cir. Mar.22, 2010). A patent that possesses an unsupported priority claim is vulnerable to invalidity attacks based on intervening art, *i.e.*, art between the priority date originally claimed and the date to which the claims are actually entitled.

For example, in *Tronzo v. Biomet, Inc.*, the Federal Circuit held that the claims at issue were not entitled to the filing date of the issued patent's parent application, and as a result were anticipated by intervening prior art. 156 F.3d 1154, 1155-56 (Fed. Cir. 1998); *see also Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1341 (Fed. Cir. 2010) (holding claims invalid over intervening art where claims did not have adequate written description support in the parent application and as a result, were not entitled to its filing date); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1311 (Fed. Cir. 2008) (affirming summary judgment of invalidity based on intervening art because patentee was not entitled to earlier filing date); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1324-25 (Fed. Cir. 2005) (upholding the Board's determination of priority in an interference proceeding where the senior party was not entitled to its earlier filing date because that application did not enable the claimed count).

In *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345–46 (Fed.Cir.2000), the court

[2] In so contending, Lilly does not concede in any way that the '124 patent disclosures satisfies any of the requirements of 35 U.S.C. § 112.

explained the need "to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." This rationale applies to a specification whose filing date is needed to antedate prior art. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319–20 (Fed.Cir.2003); *Ralston Purina Co. v. Far–Mar–Co, Inc.*, 772 F.2d 1570, 1575 (Fed.Cir.1985).

To satisfy the written description requirement the disclosure of the prior application must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession *of the invention*." *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed.Cir.1991) (emphasis in original). "[T]he invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Id.* at 1564 (emphasis in original). Claims with negative claim limitations fail to meet the written description requirement if the specification does not describe a reason to exclude the relevant limitations. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). In particular, "[n]egative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation." *Santarus*, 694 F.3d at 1351.

While a prior application need not contain precisely the same words as are found in the asserted claims, *see Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed.Cir.1995); *Purdue Pharma LP v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed.Cir.2000) (holding that the disclosure does not have to provide *in haec verba* support in order to satisfy the written description requirement), the prior application must indicate to a person skilled in the art that the inventor was "in possession" of the invention as later claimed. *Ralston*, 772 F.2d at 1575; *see also* Janice M. Mueller, *Patent Misuse Through the Capture of Industry Standards*, 17 Berkeley Tech. L.J. 623, 638 (2002) ("The [written description] requirement operates as a timing mechanism to ensure fair play in the

presentation of claims after the original filing date and to guard against manipulation of that process by the patent applicant."). "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed." *In re Huston*, 308 F.3d 1267, 1277 (Fed.Cir.2002) (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571–72 (Fed.Cir.1997)). In *Lockwood*, we held:

> While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.

107 F.3d at 1572.

Thus, to satisfy the written description requirement, "the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such a disclosure." *Tronzo*, 156 F.3d at 1159; *see also Martin v. Mayer*, 823 F.2d 500, 505 (Fed.Cir.1987) (holding that the written description requirement is "not a question of whether one skilled in the art *might* be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device") (emphasis in original). This requires that the written description actually or inherently disclose the claim element. *See TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118–20 (Fed.Cir.2001) (holding that to comply with the written description requirement the location of the spring must be actually or inherently disclosed; that the location may be obvious from the disclosure is not enough); *Tronzo*, 156 F.3d at 1159 (holding a claim invalid for failure to satisfy the written description requirement when the specification did not disclose all cup shapes literally or "inherently")

Here, the '124 patent is not entitled to a priority date of July 9, 1997 because the scope of the '124 patent claims, as construed by the Court, are not supported by the disclosures made in any prior related application. The Court has construed the claim term "inhibitor of phosphodiesterase (PDE) V" to be a selective PDE V inhibitor, which the Court has explained means that the compound is at least 20 times more effective in inhibiting PDE V than all other PDEs in accordance with the $IC_{50}$ tests allegedly set forth in the '124 Patent's specification. As discussed in further detail in Defendants' Invalidity Report and incorporated herein by reference, the $IC_{50}$ tests allegedly set forth in the '124 Patent's specification (*e.g.*, those reflected in column 7 and 8 of the '124 Patent and the referenced scientific literature) cannot be used to identify selective PDE V inhibitors in accordance with the Court's construction and, moreover, a person of ordinary skill in the art would not understand them to disclose that which has been claimed.

Assuming these fundamental defects in the '124 Patent are overcome, however, a person of ordinary skill reviewing the disclosure made in the specification of the '124 Patent and its prior applications would not understand that the inventors were in possession of an invention directed to a broad genus of compounds defined only by a particular level of effectiveness or specificity, whether 20-fold or otherwise, that are unlimited in any way to a particular chemical structure. Indeed, the specification of the '124 Patent and the prior applications to which the '124 patent claims priority do not disclose the use of a genus of inhibitors of PDE V for the treatment of BPH where the genus is defined by its level of specificity or effectiveness, including a compound which is 20 times more effective in inhibiting PDE V than all other PDEs – regardless of whether all other PDEs means the PDEs referenced in Plaintiffs' infringement reports (PDE I through PDE V), the PDEs known as of 1997 (PDE I through PDE VII), the PDEs known since at least March, 2000 (PDE I through PDE XI).

Instead, the disclosure made teaches the opposite: the inventors describe the use of a list of *identified* compounds and classes of compounds for the prophylaxis and treatment of prostatic diseases, *see, e.g.* Abstract ("The present invention pertains to the use of inhibitors of phosphodiesterase I, IV and V for the prophylaxis and treatment of prostatic diseases, *in particular the use of* ..[followed by list of compounds and classes of compounds."]); Col. 2, lines 17-27 ("Therefore, the subject matter of the invention is the *use of specific inhibitors* of sPDE I, sPDE IV and sPDE V in the prophylaxis and treatment of prostatic diseases, in particular benign prostatic hyperplasia…"), and the use of "known methods" to determine whether or not a compound is an inhibitor of "sPDE I, IV or V." (Col. 7, lines 35-39.) At most, the disclosure made would suggest the use of a compound which inhibits the activity of PDE I, IV or V in prostate tissue without any minimum threshold of selectivity towards one PDE versus other PDEs.

Moreover, and significantly, the prior disclosures do not recite a single compound which meets the definition of the claimed inhibitor of PDE V. The specification does not describe any "selective" inhibitors of PDE V which are 20 times more effective in inhibiting PDE V than all other PDEs for the PDEs known as of 1997 (PDE I through PDE VII) and the PDEs known since at least March, 2000 (PDE I through PDE XI). With regard to the compounds discussed in Plaintiffs' Amended Infringement Contentions and Infringement Reports, the only compounds that unambiguously meet the 20-fold selectivity requirement are specifically excluded from the claim.[3] Indeed, the compound specifically claimed in Claim 2 (zaprinast) falls short of the selectivity requirement with regard to *at least* PDE I and PDE VI. Moreover, the disclosure of

[3] As noted in the Invalidity Report of Dr. David Rotella, it is ambiguous and impossible to determine whether the compound identified as MY5445, which is not excluded from the scope of the claims, satisfies the 20-fold selectivity requirement when compared to PDE4.

asserted tests to measure selectivity for PDE V and the alleged 20-fold selectivity requirement set forth in the '124 Patent's specification does not disclose any compound that satisfies the test or the 20-fold selectivity requirement.

Further, there is no disclosure made which would explain or support the exclusion from the claimed method of treatment via a negative Markush limitation of the very compounds which the inventors affirmatively tout in the prior applications as being "preferred selective inhibitors" useful for the prophylaxis and treatment of BPH. (*Cf.* Claim 1 and Abstract, Col. 2, line 28-67 through Col 4 line 44.)

Finally, the Asserted Claims fail to satisfy the definiteness requirement of 35 U.S.C. §112. The claimed "selective" inhibitor of PDE V is indefinite because the specification does not disclose a test that can be used to reliably identify compounds which are 20 times more effective in inhibiting PDE V than all other PDEs. Using different methods known at the time of filing as well as today will result in the inconsistent identification of PDE V inhibitors that meet this definition of "selective," i.e. these methods will result in the same PDE V inhibitor meeting the test and failing the test.

To the extent that the '124 Patent is not afforded the claimed priority date of July 9, 1997, Defendants reserve the right to further amend these Amended Invalidity Contentions and to rely on the parent or related patents and applications of the '124 Patent as well as the Accused Instrumentality and/or Defendants' previously existing patents and patent applications as prior art. By way of example, however, the Asserted Claims of the '124 Patent would be anticipated by numerous references[4] and publications and studies relating to Lilly's own accused product,

[4] *E.g.*, Canadian Patent Application, CA 2287122, to Michale Grant Wylliee, filed October 19, 1999, published April 21, 2000, titled "Treatment of BPH with cGMP elevators"; S.A. Kaplan

Cialis® (tadalafil), as well as work performed by Lilly and ICOS under at least 35 U.S.C. 102(f) and (g).[5]

## III. IDENTIFICATION OF PRIOR ART

In addition to the references cited on the face of the '124 Patent and any patents or applications that claim priority to, priority from, or are the basis for a claim of priority in the '124 Patent (collectively, the "Related Patents"), the admitted prior art in the specification of the '124 Patent and Related Patents and the prosecution histories of the '124 Patent and Related Patents, Defendants hereby identify prior art references in (1) their Invalidity Expert Reports dated November 18, 2016 (including the report submitted by Dr. David Rotella, the report submitted by Dr. Claus Roehrborn, and the two reports submitted by Dr. Joseph A. Beavo) and (2) Exhibits A-1 through A-57 (hereinafter referred to as "Exhibit A") to their original Invalidity Contentions. The relevance of each prior art reference is discussed in the respective Invalidity Expert Reports and/or Exhibit A to the original Invalidity Contentions, which are incorporated in their entirety herein. To the extent that there is any perceived difference in the discussion of the prior art, it has resulted from the Court's claim construction orders and/or Plaintiff's Amended Infringement Contentions; consequently, the discussion in the Invalidity Expert Reports controls.

The '124 Patent is governed by the pre-AIA statutory sections of 35 U.S.C. §§ 102, 103 and 112.

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and R.R. Gonzalez, "Phosphodiesterase Type 5 Inhibitors for the Treatment of Male Lower Urinary Tract Symptoms" Rev Urol. 2007 Spring; 9(2): 73-77.

[5] On December 3, 2010, Lilly filed a supplemental NDA application with the FDA proposing new indications for Cialis®, including the treatment of the signs and symptoms of BPH, as well as the signs and symptoms of BPH when occurring with the signs and symptoms of ED. On October 6, 2011, the FDA approved Cialis® to treat the signs and symptoms of BPH, as well as the signs and symptoms of BPH when occurring with ED.

As discussed in the Invalidity Expert Reports and Exhibit A to the original Invalidity Contentions, certain prior art references disclose all of the elements of the Asserted Claims either explicitly or inherently and, therefore, anticipate the Asserted Claims under 35 U.S.C. 102, or render the Asserted Claims obvious under 35 U.S.C. 103, including obviousness stemming from a single prior art reference and the teachings conveyed by that reference in view of the skill of those of ordinary skill in the art, or via a combination of prior art references in view of the skill of those of ordinary skill in the art. Defendants further note that each and every prior art reference may also be relied upon to show the state of the art in the relevant time frames.

Defendants hereby reserve the right to make additional disclosures, including raising additional anticipation arguments based on information learned in discovery, including documents and evidence that Plaintiff has not yet produced and/or which has been improperly withheld by Plaintiff as privileged. Discovery may reveal information that affects the disclosures and contentions herein, and upon that discovery, Defendants reserve the right to update these disclosures and contentions, as appropriate. Moreover, the obviousness combinations of references provided under 35 U.S.C. § 103 are merely exemplary and are not intended to be exhaustive. Additional obviousness combinations of the references identified below are possible, including, but not limited to, after Plaintiff attempts to apply the Asserted Claims as construed by the Court, against the actions of Defendants, and Defendant reserves the right to use any such combination(s) in this litigation.

## IV. AMENDMENT TO INVALIDITY CONTENTIONS PURSUANT TO P.R.3-6

Defendants hereby incorporate by reference their (1) Invalidity Expert Reports dated November 18, 2016 (including the report submitted by Dr. David Rotella, the report submitted by Dr. Claus Roehrborn, and the two reports submitted by Dr. Joseph A. Beavo) in their entirety and (2) original Invalidity Contentions in their entirety. To the extent that there is any perceived

difference in the discussion of the prior art, it has resulted from the Court's claim construction orders and/or Plaintiff's Amended Infringement Contentions; consequently, the discussion in the Invalidity Expert Reports controls.

## V. ADDITIONAL RELEVANT ART

In addition to the prior art references, additional relevant art is discussed in Defendants' original Invalidity Contentions and Invalidity Expert Reports, all of which is incorporated herein by reference.

Dated: December 12, 2016

Respectfully submitted,

*/s/ Todd G. Vare*

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**Attorneys for Defendants Eli Lilly and Company and Brookshire Brothers, Inc.**

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via electronic mail on December 12, 2016.

*/s/ Todd G. Vare*
Todd G. Vare